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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717
7590	04/05/2004		EXAMINER	YOUNG, MICAH PAUL
Jeffrey C. Kelly, Esq. Kensey Nash Corporation 55 East Uwchlan Avenue Exton, PA 19341			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/010,304	RINGEISEN, TIMOTHY
	Examiner	Art Unit
	Micah-Paul Young	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Acknowledgment of Paper Received: Amendments/Response filed 11/28/03 and Information Disclosures Statement 02/09/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 3, 11 – 13, 15, 17, 25 – 27, 29, 30 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Reischl et al (USPN 3,553,008). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent resulting in a solution; contacting the solution with a second solvent and forming a gel; shaping the resulting gel, and removing the solvents. The polymer can be polyurethane.

Reischl et al discloses a method for making a porous polymeric material. The process comprises dissolving polyurethane in a first solvent. A second solvent is added to the solution, providing that the polyurethane is miscible in it. The gel is placed onto a substrate and the solvents are removed through evaporation. Tetrahydrofuran is disclosed as a possible first solvent. The resultant gel mixture is shaped and the solvents are removed (Abstract; col. 1, lin. 54 – col. 2, lin. 25; col. 5, lin. 20 – 70; claim 1). These disclosures render the claims anticipated.

3. Claims 1, 2, 4, 12, 15 – 17, 25, 26, 29 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Einstman et al (USPN 3,492,154). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent resulting

in a solution; contacting the solution with a second solvent and forming a gel; shaping the resulting gel, and removing the solvents. The polymer can be polyurethane.

Einstman discloses a process for making a porous polymeric sheet of polyurethane. The process comprises adding a second solvent to a polyurethane solution. The second solvent is a non-solvent, which coagulates the solution. Chloroform is disclosed as the second non-solvent (Abstract; col. 5, lin. 3 – 47; col. 7, lin. 47 – 63; claim 1). These disclosures along with others render the claims anticipated.

4. Claims 1, 8, 10, 15, 16, 23, 24, 26, 27, 29, 31, and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al (USPN 5,077,049). The claims are drawn to a process for making a porous polymeric material comprising the steps of dissolving a polymer in a solvent resulting in a solution; contacting the solution with a second solvent and forming a gel; shaping the resulting gel, and removing the solvents. The polymer can be polyurethane. The porous polymeric material further acts as a scaffold for a biologically active agent.

Dunn et al discloses a process for making a porous polymeric implant. The implant comprises biologically active agents such as growth hormones and the like (col. 6, lin. 51 – col. 7, lin. 2). Combining a polymer solution with a coagulating solvent forms the porous implant. The polymer solution comprises a biocompatible polymer dissolved in a solvent. The polymer can be polyurethane, and the second solvent can be dimethyl sulfoxide, or tetrahydrofuran (col. 5, lin. 7 – 51). The polymer/solvent/agent mixture is injected into the body where it continues to coagulate and takes on the shape of the implant site. The solvents permeate out of the polymeric body leaving pores (Ibid.) These disclosures along with others (examples, claims) render these claims anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 6, 7, 9, 11, 18 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Einstman et al (USPN 3,492,154) in view of Helmus et al (USPN 5,447,724) and Le Noane (USPN 4,769,286). The claims are drawn to a process for making a polymeric material where the polymer includes a biologically active agent. Also the polymeric material is contacted with various medical materials.

As discussed above Einstman discloses a porous polymeric material. The material is made of polyurethane and comprises the solvents of the instant claims. What is lacking is a disclosure of biological active or medical materials being contacted with the polymeric material of Einstman. Einstman suggests that the polymers of the invention can be used in combination

with biological and supporting materials (col. 1, lin. 37 – 41). Also porous polymeric coatings are well known in the art of medical devices.

Helmus discloses medical devices where a surface comprises porous polymeric composition holding a biologically active compound (Abstract). The device can be in the form of a suture or any implantable medical device. The device can also aid in adhesion to the body. The polymeric coating, which contact the surface of the body, and releases the biological active agent, can be made of the polymers of the instant claims (col. 2, lin. 15 – 65).

Le Noane teaches reinforcing materials such as fibers, rings and other devices. The devices comprise porous polymers incorporated into the structure of the fibers (Abstract). The polymers for use in the materials of the reference are within the instant claims (claims).

With regard to claims 6, 7 and 9 which are drawn to the order in which the active agent is added to the polymeric compound, it is the position of the examiner that such limitations do not carry patentable weight in light of the prior art. These limitations are well within the level of skill in the art, to manipulate and configure in order to achieve the best release of the active compounds. Barring a showing of criticality to the order in which the active agent is added, the claims will remain obviated in view of the prior art.

With these things in mind a skilled artisan would have been motivated to combine the porous polymer of Einstman with the implantable devices of Helmus or supporting structures of Le Noane. The porous polymer would have allowed for the release of active agents in Helmus and provided a supportive substrate for the threads, fibers and other devices of Le Noane. The porous polymer would aid in the adhesion of the implant of Helmus. A skilled artisan would expect the porous polymer to both support and be able to release active agents. It would have

been obvious to combine the teachings with an expected result of a supportive, active-agent releasing device.

8. Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (USPN 5,077,049) in combination with Reischl et al (USPN 3,553,008).

As discussed above Dunn et al discloses a process for making a porous polymer. The reference discloses various solvents including dimethyl sulfoxide (col. 5, lin. 37 – 51). The reference discloses a polymer/solvent/agent combination, which is gelled and has its solvent removed. What is lacking is a disclosure of the order in which the solvent is used. The polymer is presented in the form of a solution of dissolved polymer, where the second polymer acts as the gelling polymer. Tetrahydrofuran is well known as a dissolving polymer as seen in Reischl et al. Reischl discloses the solvent as a dissolving solvent for polyurethane. Dunn discloses dimethyl sulfoxide as a gelling second solvent. A skilled artisan would be motivated to combine the solvents since both reference teach the creation of a porous polymer. The solvents used by both Dunn and Reischl are well known in the art of making porous polymers.

It would have been obvious to dissolve the polymer with the tetrahydrofuran of Reischl and further gel the polymer with solvents of Dunn. A skilled artisan would have been motivated to combine the teachings as such in order to insure the proper porosity of the resultant gelled polymer. A skilled artisan would expect gelled polymer capable of carrying active agents.

Response to Arguments

9. Applicant's arguments filed 11/23/03 have been fully considered but they are not persuasive. Applicant argues that:

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a. The second solvents of Reischl, Einstman and Dunn are not gelling solvents, and do not impart the same gelling feature as that of the instant claims.

b. There is no motivation to combine Helmus and Le Noane, and do not solve the problems of Einstman.

With regard to argument a., it is the position for the examiner that since each reference discloses a polymer that is gelled, though the second solvent is not explicitly called a gelling solvent, the compounds perform identically to that of applicant. Namely a gel is formed from the addition of the second solvent. With regard to Einstman in particular chloroform is used as the second solvent. This solvent is listed by applicant as being applicable to the invention as a possible second “gelling” solvent. With regard to Dunn, the resultant product is nearly identical to that of applicant. A polymer dissolved in a solvent and gelled with a second polymer is the essence of the claimed invention. Applicant argues that the prior art does not disclose a appreciation for the functions of the primary and secondary solvents, yet applicant has yet to establish a functional difference between the polymers created in the instant claims and those of the prior art. Also applicant argues that since the second solvents are simply non-solvents and not true gelling solvents, they cannot possibly anticipate the instant invention. The claims do not exclude the inclusion of non-solvents, and only stipulate that the second solvent cause a gelation. This is the case in each and every anticipatory reference cited, and the burden is shifted to applicant to provide evidence of a functional difference between the polymers of the instant claims and those of the prior art. Also applicant is reminded that the present disclosure still only enables applicant for organic solvents, and not all solvents capable of dissolving a polymer. Dunn discloses a thermoplastic setting system where a dissolved polymer is combined with a

second solvent, which coagulates the solution and solidifies it. The examiner sees no difference between gelation and coagulation, and invites applicant to provide evidence of such a patentable difference.

With regard to argument b., Einstman provides sufficient motivation by suggesting that the polymers of the invention (Einstman) can be included on supportive medical materials. These devices can further include biological agents such as anti-bacterial agents to fight infections. Helmus and La Noane provide supportive medical devices, which comprise porous polymeric coatings. It would be well within the level of skill in the art to combine the polymers taught in Einstman with the devices of either Helmus or La Noane, since the porous polymer would provide a support for active agents delivered or released by the device. With regard to the combination of Dunn and Reischl, each reference discloses polyurethane being dissolved and processed by organic solvents namely DMSO and tetrahydrofuran respectively.

Tetrahydrofuran is well known as a dissolving polymer as seen in Reischl et al. Reischl discloses the solvent as a dissolving solvent for polyurethane. Dunn discloses dimethyl sulfoxide as a gelling second solvent. A skilled artisan would be motivated to combine the solvents since both reference teach the creation of a porous polymer. For thee reasons the claims remain obviated by the art.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MP Young

Micah-Paul Young
Examiner
Art Unit 1615 THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600